



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,269	01/30/2004	Kurt-Robert Kappeler	010751-069	4842

21839 7590 02/23/2006

BUCHANAN INGERSOLL PC
(INCLUDING BURNS, DOANE, SWECKER & MATHIS)
POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER

AUGHENBAUGH, WALTER

ART UNIT	PAPER NUMBER
----------	--------------

1772

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/767,269

Applicant(s)

KAPPELER, KURT-ROBERT

Examiner

Walter B. Aughenbaugh

Art Unit

1772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-18 is/are pending in the application.
- 4a) Of the above claim(s) 15-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/2/04, 9/10/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1 and 3-14, in the reply filed on December 8, 2005 is acknowledged. The traversal is on the ground(s) that there would be no serious burden to search both groups because a search for the subject matter of one Group "necessarily would encompass a search [for the subject matter of the other Group]". This is not found persuasive because method claim 15 requires steps which recite structure that is not required by article claim 1: article claim 1 does not require that the layers are extruded, but that the materials from which the layers are formed is capable of being extruded.

The requirement is still deemed proper and is therefore made FINAL.

Specification

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

3. The abstract of the disclosure is objected to because it uses phrases that can be implied ("The present invention relates to" and "according to the present invention") and legal phraseology ("said" and "comprising"). Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Stone et al.

In regard to claim 1, Stone et al. teach a multi-layer hose (balloon sheath, item 40) comprising an opaque, extrudable first layer (item 42), an opaque, extrudable second layer (item 44) connected to the first layer (col. 5, lines 29-32 and Fig. 2) and at least one marking section that is arranged between the first layer and the second layer (radiopaque marker, col. 5, lines 43-50) and that is adapted to be read making use of X-rays (since it is radiopaque). The first and second layers of Stone et al. are opaque because the materials of the layer are polymeric materials that are not disclosed as transparent (any layer that is not transparent has some degree of opacity). The first and second layers of Stone et al. are extrudable because Stone et al. teach that the first layer (item 42) is formed of an elastic material such as latex or silicone (col. 5, lines 51-57), both of which are extrudable as evidenced by col. 21, lines 13-21 of U.S. 5,928,200 to Thorne et al., and that the second layer (item 44) is formed of such materials as PET and nylon, both of which are extrudable as evidenced by col. 3, lines 8-12 of U.S. 6,443,925 to Schaible et al.

In regard to claim 3, Stone et al. teach that the first layer (item 42) is formed of an elastomer such as latex or silicone (col. 5, lines 51-57).

Art Unit: 1772

In regard to claim 4, Stone et al. teach that the elastomer is a rubber because elastomers are rubbers.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stone et al. in view of Hostettler et al.

Stone et al. teach the hose as discussed above. Stone et al. teach that the outer later, item 42, is formed from a wide variety of elastic materials (col. 5, lines 51-57).

Stone et al. fail to explicitly teach that the rubber is an ethylene acrylate rubber.

Hostettler et al., however, disclose that ethylene/alkyl acrylate copolymer rubbers are a suitable material for use in catheters (col. 9, lines 6-13). Therefore, one of ordinary skill in the art would have recognized to have used the ethylene/alkyl acrylate copolymer rubber taught by Hostettler et al. as the elastic material of outer later, item 42, of Stone et al. since ethylene/alkyl

Art Unit: 1772

acrylate copolymer rubber is a well known material for use in catheters as taught by Hostettler et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the ethylene/alkyl acrylate copolymer rubber taught by Hostettler et al. as the elastic material of outer later, item 42, of Stone et al. since ethylene/alkyl acrylate copolymer rubber is a well known material for use in catheters as taught by Hostettler et al.

8. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stone et al. in view of Shu.

Stone et al. teach the hose as discussed above.

Stone et al. fail to explicitly teach that the radiopaque marker is formed by an ink.

Shu, however, disclose a balloon catheter comprising radiopaque ink as a radiopaque marker or markers for tracking the exact location of the balloon catheter inside a patient (col. 9, line 61-col. 10, line 11). Therefore, one of ordinary skill in the art would have recognized to have used a radiopaque ink as the radiopaque marker or markers of Stone et al. since radiopaque ink is a well known radiopaque marker for balloon catheter devices as taught by Shu.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a radiopaque ink as the radiopaque marker or markers of Stone et al. since radiopaque ink is a well known radiopaque marker for balloon catheter devices as taught by Shu.

9. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stone et al. in view of Carden, Jr. et al.

Stone et al. teach the hose as discussed above. Stone et al. teach that suitable materials for the markers are platinum and gold (col. 4, lines 51-57).

Stone et al. fail to explicitly teach that the radiopaque markers are provided in a longitudinally spaced relationship with one another in a recurring mode of arrangement.

Carden, Jr. et al. disclose an implantable biomedical plastic strand (item 900, Fig. 11) that comprises bands of an X-ray absorbing material such as gold or platinum as radiopaque markers that are provided in a longitudinally spaced relationship with one another in a recurring mode of arrangement (Fig. 11 and col. 20, lines 30-35 and col. 21, lines 14-26). Therefore, one of ordinary skill in the art would have recognized to have applied the radiopaque bands of Stone et al. in a longitudinally spaced relationship with one another in a recurring mode of arrangement in order to enable a healthcare worker to precisely visualize the location of the hose within the body and of particular portions of the hose along its length since it is well known to provide a medical implant with radiopaque markers in a longitudinally spaced relationship with one another in a recurring mode of arrangement for visualization of the device as taught by Carden, Jr. et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have applied the radiopaque bands of Stone et al. in a longitudinally spaced relationship with one another in a recurring mode of arrangement in order to enable a healthcare worker to precisely visualize the location of the hose within the body and of particular portions of the hose along its length since it is well known to provide a medical implant with radiopaque markers in a longitudinally spaced relationship with one another in a recurring mode of arrangement for visualization of the device as taught by Carden, Jr. et al.

Art Unit: 1772

10. Claims 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone et al. in view of Shu and in further view of Carden, Jr. et al. and in further view of Kelderman et al.

Stone et al. and Shu teach the hose as discussed above. Stone et al. and Shu fail to explicitly teach that the ink contains an iodine compound and that the ink contains potassium iodide. Carden, Jr. et al., however, disclose an implantable biomedical plastic strand (item 900, Fig. 11) that comprises bands of radiopaque ink that are printed onto the plastic strand via inkjet printing technology (col. 20, lines 30-35 and col. 21, lines 14-23). Furthermore, Kelderman et al. teach an inkjet ink that comprises potassium iodide as a dye (KI, an iodine compound, col. 7, lines 59-65 and col. 1, line 61-col. 2, line 8). Therefore, one of ordinary skill in the art would have recognized to have printed radiopaque ink onto the hose taught by Stone et al. and Shu via inkjet printing technology since it is well known to print radiopaque ink onto a medical device via inkjet printing technology as taught by Carden, Jr. et al. and to have used an inkjet ink comprising potassium iodide as the ink since potassium iodide is a well known dye for use in inkjet ink as taught by Kelderman et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have printed radiopaque ink onto the hose taught by Stone et al. and Shu via inkjet printing technology since it is well known to print radiopaque ink onto a medical device via inkjet printing technology as taught by Carden, Jr. et al. and to have used an inkjet ink comprising potassium iodide as the ink since potassium iodide is a well known dye for use in inkjet ink as taught by Kelderman et al.

11. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stone et al. in view of Shu and in further view of Carden, Jr. et al. and in further view of Carroll.

Stone et al. and Shu teach the hose as discussed above. Stone et al. and Shu fail to explicitly teach that the ink contains an iodine compound and that the ink contains iopamidole. Carden, Jr. et al., however, disclose an implantable biomedical plastic strand (item 900, Fig. 11) for the treatment of tumors (col. 1, lines 7-9 and 35-47) that comprises bands of radiopaque ink that are printed onto the plastic strand via inkjet printing technology (col. 20, lines 30-35 and col. 21, lines 14-23). Furthermore, Carroll discloses that ethanolamine oleate iopamidole is used in the preparation of a tumor for treatment (col. 5, line 58-col. 6, line 2 and col. 3, line 66-col. 4, line 18). Therefore, one of ordinary skill in the art would have recognized to have printed radiopaque ink onto the hose taught by Stone et al. and Shu via inkjet printing technology since it is well known to print radiopaque ink onto a medical device via inkjet printing technology as taught by Carden, Jr. et al. and to have used an inkjet ink comprising ethanolamine oleate iopamidole as the ink so that the ink may contribute to the preparation of a tumor for treatment as taught by Carroll when the device taught by Stone et al., Shu and Carden, Jr. et al. is used for the treatment of a tumor.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have printed radiopaque ink onto the hose taught by Stone et al. and Shu via inkjet printing technology since it is well known to print radiopaque ink onto a medical device via inkjet printing technology as taught by Carden, Jr. et al. and to have used an inkjet ink comprising ethanolamine oleate iopamidole as the ink so that the ink may contribute to the preparation of a tumor for treatment as taught by Carroll when the device taught by Stone et al., Shu and Carden, Jr. et al. is used for the treatment of a tumor.

Art Unit: 1772

12. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stone et al. in view of Shu and in further view of Carden, Jr. et al. and in further view of Gundlach et al.

Stone et al. and Shu teach the hose as discussed above. Stone et al. and Shu fail to explicitly teach that the ink contains an iodine compound and that the ink contains potassium bromide. Carden, Jr. et al., however, disclose an implantable biomedical plastic strand (item 900, Fig. 11) that comprises bands of radiopaque ink that are printed onto the plastic strand via inkjet printing technology (col. 20, lines 30-35 and col. 21, lines 14-23). Furthermore, Gundlach et al. disclose an inkjet ink that comprises potassium bromide (col. 38, lines 1-42 and col. 1, lines 5-9) as a salt (col. 17, line 66-col. 18, line 1 and col. 19, lines 17-23) that improves the solubility or stability of the dye in the ink vehicle (col. 20, lines 20-27). Therefore, one of ordinary skill in the art would have recognized to have printed radiopaque ink onto the hose taught by Stone et al. and Shu via inkjet printing technology since it is well known to print radiopaque ink onto a medical device via inkjet printing technology as taught by Carden, Jr. et al. and to have used an inkjet ink comprising potassium bromide as the ink since potassium bromide is a well known additive to inkjet ink for improving the solubility or stability of the dye in the ink vehicle as taught by Gundlach et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have printed radiopaque ink onto the hose taught by Stone et al. and Shu via inkjet printing technology since it is well known to print radiopaque ink onto a medical device via inkjet printing technology as taught by Carden, Jr. et al. and to have used an inkjet ink comprising potassium bromide as the ink since potassium bromide is a well known additive to

Art Unit: 1772

inkjet ink for improving the solubility or stability of the dye in the ink vehicle as taught by Gundlach et al.

13. Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone et al. in view of Shu and in further view of Carden, Jr. et al.

Stone et al. and Shu teach the hose as discussed above.

In regard to claim 11, the limitation “wherein the ink is applicable to the hose by means of a printer” has been given little patentable weight since the method used to apply the ink to the hose is not germane to the issue of patentability of the hose itself. In regard to claims 12 and 13, the limitations of these claims have not been given patentable weight since the type of apparatus used to apply the ink to the hose (in regard to claims 11-13) are not germane to the issue of patentability of the hose itself.

Stone et al. and Shu fail to explicitly teach that the ink is applicable to the hose by means of a printer.

Carden, Jr. et al., however, disclose an implantable biomedical plastic strand (item 900, Fig. 11) that comprises bands of radiopaque ink that are printed onto the plastic strand via inkjet printing technology (col. 20, lines 30-35 and col. 21, lines 14-23). Therefore, one of ordinary skill in the art would have recognized to have printed radiopaque ink onto the hose taught by Stone et al. and Shu via an inkjet printer since it is well known to print radiopaque ink onto a medical device via an inkjet printer as taught by Carden, Jr. et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have printed radiopaque ink onto the hose taught by Stone et al. and Shu via an

Art Unit: 1772

inkjet printer since it is well known to print radiopaque ink onto a medical device via an inkjet printer as taught by Carden, Jr. et al.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B. Aughenbaugh whose telephone number is 571-272-1488. While the examiner sets his work schedule under the Increased Flexitime Policy, he can normally be reached on Monday-Friday from 8:45am to 5:15pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is to 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Walter B. Aughenbaugh

02/21/06

WBA


HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

2/20/06